

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

CHARLES A. HARTJEN, M.D.

Plaintiff,

v.

CROSS MEDICAL PRODUCTS, INC.

Defendant.

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Case No.: MJG06CV2938

SECOND AMENDED COMPLAINT

Plaintiff Charles A. Hartjen, M.D. (“plaintiff” or “Dr. Hartjen”), for his Complaint against defendant Cross Medical Products, Inc. (“defendant” or “Cross Medical”), hereby alleges as follows:

SUBJECT MATTER JURISDICTION AND VENUE

1. This is an action under the Patent Act of the United States, 35 U.S.C. § 256, seeking a declaration that plaintiff is a co-inventor of two patents owned by Cross Medical, and further claiming that Cross Medical has been unjustly enriched by failing and refusing to recognize plaintiff as a co-inventor of those patents.

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 in that it is an action between citizens of different states and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000. This Court also has subject matter jurisdiction over the matters complained pursuant to 35 U.S.C. § 256 and 28 USC. §§ 1331, 1338 and 2201.

3. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) in that Cross Medical resides in this district by virtue of the fact that its contacts in this district are sufficient to subject it to personal jurisdiction in this district.

THE PARTIES

4. Plaintiff is a Maryland resident and an orthopedic surgeon having his principal place of business at One Texas Station Court, Suite 300, Lutherville, Maryland 21093.

5. On information and belief, Cross Medical is a Delaware corporation having its principal place of business at 191 Technology Drive, Irvine, California 92618.

UNDERLYING FACTS

6. On information and belief, Cross Medical is part of an independent public medical device company that offers orthopedic surgical implants used to stabilize and align the bones of a patient's spine.

7. Beginning in the mid-1980s, Cross Medical entered into a relationship with several orthopedic surgeons by which the surgeons agreed to work with and consult with Cross Medical (and its predecessor-in-interest, Danninger Medical Technology, Inc.) in connection with the development of spinal products.

8. Over the next several years, one of those surgeons, Dr. Ronald M. Puno ("Puno"), worked together with Cross Medical's Vice President of Product Development, Philip Mellinger ("Mellinger"), in the development of spinal products.

9. At all times relevant to this action, Mr. Mellinger was an officer and/or employee of Cross Medical.

10. On November 1, 1994, United States Patent No. 5,360,431 (the "431 Patent"), entitled "Transpedicular Screw System and Method of Use" was issued to Puno and Mellinger.

Puno and Mellinger had previously assigned to Cross Medical all of their right, title and interest in what became the '431 Patent.

11. On December 12, 1995, United States Patent No. 5,474,555 (the “555 Patent”), entitled “Spinal Implant System” was issued to Puno and Mellinger. Puno and Mellinger had previously assigned to Cross Medical all of their right, title and interest in what became the '555 Patent.

12. The development of the '431 and '555 Patents was done under the direction of and for the benefit of Cross Medical.

13. In early 1988, Cross Medical enlisted the assistance of Dr. Hartjen to serve as a clinical investigator exploring the use and efficacy of a spinal pedicle screw that was a predecessor to the '431 and '555 Patent devices. This pedicle screw was identified at the time as the “PWB I”.

14. As part of that clinical investigation, Dr. Hartjen was requested to perform operations inserting the PWB I pedicle screw system in patients, and then to report the results of the implantation and performance of the PWB I system.

15. In mid-1988, Dr. Hartjen traveled to Louisville, Kentucky to perform practice insertions of the PWB I device on cadavers in preparation for its use on patients in the clinical study.

16. Thereafter, Dr. Hartjen returned to Baltimore, where he began his clinical investigation using the PWB I device on patients at the Greater Baltimore Medical Center.

17. On information and belief, Dr. Hartjen was one of the first, if not the first clinical investigator to insert the PWB I device in patients as part of the clinical study.

18. In January 1989, Dr. Hartjen performed his first such operation utilizing the PWB I device.

19. During the course of that operation, Dr. Hartjen experienced difficulty in the implantation and securitization of the PWB I system.

20. Specifically, the PWB I system required the surgeon, after inserting the screw into the patient's spine, to insert a rod into adjoining pedicle screws, and to tighten that rod into the pedicle screw by tightening a nut upwards from the patient's spine onto a cap and towards the top of the screw.

21. Dr. Hartjen found that the bottom-tightening feature of the PWB I device was rendered difficult to employ, both because of the awkward position of the nut vis-à-vis the surgeon, and because of the presence of blood, bone graft and soft tissue in the area.

22. Based on his experience in his first surgical procedure utilizing the PWB I system, Dr. Hartjen reported to Cross Medical and the named inventors of the '431 and '555 Patents both the existence of this difficulty, and a suggestion for solving this problem.

23. Specifically, Dr. Hartjen suggested that the problem to be solved with the PWB I device was the difficulty encountered in tightening the nut in live patients because of the nut's position and the presence of blood and tissue.

24. Further, Dr. Hartjen suggested to Cross Medical and the named inventors of the '431 and '555 Patents a solution to the problem: he suggested that the nut and the collar onto which it locked be relocated from beneath the spine rod to a position above the rod to make it easier to assemble and tighten.

25. Not surprisingly, Cross Medical and the named inventors of the '431 and '555 Patents thereafter adopted Dr. Hartjen's suggestion, and modified the PWB I device to employ the "top loading" feature suggested by Dr. Hartjen.

26. This modified device came to be identified by Cross Medical as the "PWB II" device, variations of which are the subject of both the '431 and '555 Patents.

27. Evidencing the import and efficacy of Dr. Hartjen's suggestion, one of the identified inventors of the '431 and '555 Patents co-authored a paper on the development of the '555 device entitled: "The Puno-Winter-Byrd (PWB) Spinal System for Transpedicular Fixation of the Lumbar Spine."

28. In that paper, the authors discussed the problem identified by Dr. Hartjen, and the employment of his proposed solution by stating as follows:

There were several things learned during the pilot phase of this study. The surgeons found that implantation of the first version (Fig. 17.3: PWB I) was somewhat tedious because of the implant design. It was technically difficult to position the wrench when the nut was tightened, since it required that the nut be advanced from under the rod. Although it provided satisfactory fixation of the rod, the design was not "user friendly". A design improvement was in order and led to the development of the PWB II (Fig. 17.1), where the nut is applied from the top of the rod.

See Exhibit 1 to Complaint at p. 293 (emphasis supplied).

29. Cross Medical's internal documents likewise confirm the genesis of the change from the PWB I system to the PWB II system, as well as its timing.

30. For example, in a May 15, 1990 memorandum by The Buckman Company (which managed the investigational protocol on Cross Medical's behalf) to Cross Medical and to surgeons participating in the study, Buckman wrote that "Based on the input from the operating surgeons for these 40 patients, the device has been modified to reduce the technical difficulty in implanting the system. The modification involved relocating the locking collar from beneath the

spine rod to a position above the rod to facilitate intraoperative assembly.” Exhibit 2 to Complaint (emphasis supplied).

31. At all relevant times, Cross Medical was aware of Dr. Hartjen’s participation in the development of and his contributions to the devices covered by the ‘431 and ‘555 Patents.

32. Notwithstanding the fact that plaintiff made significant contributions to the conception of the devices covered by the ‘431 Patent and the ‘555 Patent, he was omitted as a co-inventor of these patents.

33. Cross Medical has a significant economic stake in the validity of the patents involved here and hence in the correct inventorship designations on the patents.

COUNT I
(Correction of Inventorship Under 35 U.S.C. § 256)

34. Plaintiff incorporates by reference the allegations contained within paragraphs 1 through 33 of this Complaint as if fully set forth herein.

35. By virtue of his significant contributions to the conception of the devices covered by the ‘431 Patent and the ‘555 Patent, plaintiff should have been named as a co-inventor of these patents pursuant to 35 U.S.C. § 113.

36. Plaintiff’s omission as a co-inventor of the ‘431 and ‘555 Patents was not the result of any deceptive intent on plaintiff’s part.

37. Pursuant to 35 U.S.C. § 256, this Court may order correction of the patent on notice and hearing of all parties concerned.

WHEREFORE, plaintiff prays for a declaration that he is a co-inventor of the ‘431 Patent and the ‘555 Patent, and that the Court direct the Director of the United States Patent and Trademark Office to issue a certificate accordingly.

COUNT II
(Unjust Enrichment)

38. Plaintiff incorporates by reference the allegations contained within paragraphs 1 through 37 of this Complaint as if fully set forth herein.

39. Plaintiff conferred a benefit on Cross Medical by virtue of his contributions to the development of the '431 and '555 devices.

40. Cross Medical has knowingly retained that benefit, and has been unjustly enriched by the failure to name plaintiff as an inventor.

41. Specifically, Cross Medical has at all times acted as if it was the exclusive owner of the '431 and '555 Patents. This has permitted Cross Medical to exclusively license these devices, as well as bring actions against others for infringement.

42. Had Dr. Hartjen been properly named as a co-inventor, Cross Medical would not have been able to exclusively license these devices or to bring infringement actions without plaintiff's consent or participation.

43. Cross Medical has realized additional and incremental profits, royalties and infringement recoveries attributable to its ability to exclude others from selling competing devices.

44. In addition, and on information and belief, Cross Medical would have had to pay more to obtain an assignment from plaintiff had he been named as an inventor than it paid merely to obtain such an assignment from the named inventors.

45. Specifically, and on information and belief, as an employee of Cross Medical at the time that the devices were patented, Mr. Mellinger had a pre-existing obligation to share with Cross Medical his interests in the patented devices.

46. On information and belief, the cost to Cross Medical to obtain an assignment from an employee such as Mr. Mellinger was significantly less than required to obtain an assignment from a third party such as plaintiff.

47. Under these circumstances, it would be inequitable for Cross Medical to accept and retain the benefits it has realized from plaintiff's actions and contributions.

WHEREFORE, plaintiff demands judgment against Cross Medical in an amount to be proven at trial, plus pre-judgment and post-judgment interest and such other and further relief as this Court deems appropriate.

**COUNT III
(Quantum Meruit)**

48. Plaintiff incorporates by reference the allegations contained within paragraphs 1 through 47 of this Complaint as if fully set forth herein.

49. Plaintiff provided valuable services to Cross Medical through his work on the patented devices.

50. Plaintiff's services were accepted by Cross Medical to its great benefit.

51. Plaintiff's services were provided under such circumstances that Cross Medical knew of their benefit and knew that plaintiff would expect to be paid for those services.

52. It would be unjust and inappropriate for Cross Medical to retain the benefit of those services without compensating plaintiff for their reasonable value.

WHEREFORE, plaintiff demands judgment against Cross Medical in an amount to be proven at trial, plus pre-judgment and post-judgment interest and such other and further relief as this Court deems appropriate.

Respectfully submitted,

TOBIN, O'CONNOR, EWING & RICHARD

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JURY DEMAND

A trial by jury is hereby demanded on all issues triable to a jury.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 28th day of February, 2007, a true and correct copy of the First Amended Complaint was sent by first-class, postage pre-paid U.S. mail to:

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